a multinational study that assessed the effectiveness of DA using the SilverHawkTM and TurboHawkTMPlaque ExcisionSystems (Covidien/ev3, Plymouth, MN) for treatment of peripheral arterial disease.

Methods: The DEFINITIVE LE study enrolled 800 patients. Of those, 70 had CLI and at least one infrapopliteal target lesion treated with DA. Endpoints and adverse events were assessed by independent core laboratories and a Clinical Events Committee. The primary endpoint for the CLI cohort was freedom from major unplanned amputation of the target limb at 12 months.

Results: Within the DEFINITIVE LE study, 70 patients with CLI had 96 infrapopliteal target lesions treated with DA. The breakdown by Rutherford Clinical Category (RCC) was as follows: RCC 4: 34%, RCC 5: 63%, and RCC 6: 3%.The mean age was74 years, 56% were male and79% had diabetes.The mean lesion length was 6.0 cm and the mean baseline stenosis was 77%. One-third (33%) of lesions were occluded,31% of lesions were calcified and 39% had inflow disease treated during the same procedure.Periprocedural complications included 1 (1%) perforation and 3 (4%) embolizations; there were no flow-limiting dissections. At 12 months, limb salvage was 94%, primary patency was 78% and freedom from target lesion revascularization (TLR) was 87%, per Kaplan-Meier estimates. Complete wound healing at 12 months was 68%.

Conclusions: This prospective assessment of DA for treatment of Infrapopliteal lesions in CLI patients showed low complication rates and high rates of limb salvage,freedom from TLR, and primary patency at 12 months comparable to recent drug eluting stent trials. These findings should be taken into consideration when treating this challenging group of patients.

TCT-66

Risk stratification after endovascular treatment in claudicant patients with Iliofemoral artery disease

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Background: The natural history of patients with intermittent claudication (IC) has been reported. However, little is known about prognosis of claudicant patients after endvascular therapy (EVT).

Methods: This study was performed as a large-scale multicenter, retrospective registry. A total of 2,930 consecutive patients (mean age, 71.5±8.9 years, 78.7% male) with IC treated by EVT for a de novo ilio-femoral lesion were enrolled. The primary outcome measure was overall survival, and the secondary outcome measure were freedom from major adverse cardiovascular events (MACE; all-cause death (ACD), myocardial infarction and stroke), and major adverse cardiovascular and limb events (MACLE; any repeat revascularization for limb and leg amputation in addition to MACE).

Results: The overall survival rate was 97.2%, 90.8%, and 83.4% at 1, 3 and 5 years. The cause of death was cardiovascular in 42.8%. Freedom from MACE (MACLE) was 96.7% (84.5%), 88.6% (68.1%), and 77.3% (58.7%) at 1, 3and 5 years. On multivariate analysis performed logistic regression by prespecified risk factors, elderly age, Dialysis, LV dysfunction, Insulin administration, complication of hematoma, Coronary artery disease, SFA plus iliac lesions were found to be positive independent predictors of ACD. ACEI/ARB, Ca-antagonist administration were negative predictor. Risk stratification of ACD based on these seven positive predictors. Elderly age, Dialysis, LV dysfunction, Insulin administration and complication of hematoma were scored as 2 points. The others were assigned 1 point each. The scores of 0 to 2, 3 to 5, and >6 points were classified as low-, moderate- and high-risk patients, respectively. The overall survival rate was significantly lower in the high-risk patients than other two groups (90.1% vs. 78.6% vs. 53.5% at 5years, P<0.0001; log-rank test).

Conclusions: The prognosis after EVT for patients with IC was relative good. However, that for high risk patients with IC was extremely poor.

Invasive Imaging

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TCT-67

The First Establishment of Early Healing Profile, 9-month Neointimal Growth, and 24 Months Outcomes of the Dual Therapy Endothelial Progenitor Cell Capturing Sirolimus-eluting Stent as Assessed by Longitudinal Sequential Optical Coherence Tomography: The EGO-COMBO Study.

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Background: The EGO-COMBO study is the first study ever designed to establish the healing profile of a DES, and benefits of the dual therapy COMBO Stent (OrbusNeich, US), a hybrid version of the EPC-capturing Genous Stent plus a 5μg/mm abluminal sirolimus coating, using sequential OCT FUs to 24 months.

Methods: In this prospective single center study, 61 patients (9M DAPT) received 3 longitudinal sequential OCTs at baseline (for optimal stent apposition), at early FU (4 monthly group 2nd to 5th month, in 1:2:2:1 ratio, for % strut coverage using 6 Categories), then at 9M (for late loss and OCT neointima), and clinical FU to 12M. With a 2nd approved protocol, a 24M OCT FU was initiated for long term outcomes. All clinical event adjudication, QCA & OCT analyses were undertaken by CRF Core Lab., NY.

Results: 61 patients (33% DM) received 88 COMBO stents (size 3.06±0.39mm & length 23.9±7.62mm). Early strut coverage (OCT Cat. D to F) increased from 84.3, 90.2, 90.5, to 92%; interpolated 100% coverage at 150 days. 9M OCT FU Rate was 100%; only 1 TLR treated by POBA (MACE Rate 1/61 = 1.64%). 9M late loss was 0.24±0.36mm, OCT NIT 0.157mm & NIA 1.445mm2. At 24M, 1 case lost to FU (migrated to China), another elderly patient died from VF after days of recurrent chest pain without seeking advice. All remaining 59 cases were entirely asymptomatic & 18 declined the 4th OCT FU (24M Clinical FU Rate 58/59 = 98.3% & OCT FU Rate 40/58 = 69.0%). To date, 39 patients have had the restudy, all showing excellent results (late loss catch up <0.1mm; OCT NIT Δ 0.002mm; NIA Δ 0.13mm2), without neoatherosclerosis or late stent thrombosis (not even micro-thrombi by OCT). Thus, 24M MACE Rate 2/61 = 3.28%; final core lab. results pending.

Conclusions: Using stringent longitudinal sequential OCT FUs with core lab. adjudication, the dual therapy COMBO stent is the first DES ever with a healing profile established and appears to be a novel device (excellent healing with optimal neointimal suppression without late stent thrombosis) with durable 24M outcomes. This longitudinal sequential OCT FU approach may be adopted to guide development of any new stent platform, appropriate DAPT duration, and to predict (prevent) late stent thrombosis.

TCT-68

Does IVUS Reduce Stent Thrombosis with DES? Two-year results from the prospective, multicenter ADAPT-DES study

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Background: Whether IVUS guidance reduces the long-term rates of stent thrombosis (ST) after drug-eluting stent (DES) implantation is controversial.

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